# Exhibit C

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Attorneys for Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.



IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

| | |
|---|---|
| IN RE: Bard IVC Filters Products Liability Litigation, | No. 2:15-MD-02641-DGC<br><br>**DEFENDANTS C. R. BARD, INC.'S AND BARD PERIPHERAL VASCULAR, INC.'S RESPONSES AND OBJECTIONS TO PLAINTIFFS' NOTICE OF DEPOSITION PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 30(B)(6) AND RELATED REQUESTS FOR PRODUCTION OF DOCUMENTS** |

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively referred to herein as "Bard"), by and through counsel, respond to Plaintiffs' Notice of Deposition Pursuant to Federal Rule of Civil Procedure 30(b)(6) and Related Requests for Production of Documents, served on November 5, 2015 ("Notice"), as follows:

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**SUBJECT MATTER IDENTIFIED IN EXHIBIT "A"**

**TOPIC NO. 1:**

**All communications with FDA officials regarding the subject matter and content of the warning letter issued by FDA on July 13, 2015 including but not limited to communications described in the letter.**

**RESPONSE:**

Bard will produce a witness to testify generally concerning Bard's communications with FDA officials regarding the subject matter and content of the FDA's July 13, 2015 Warning Letter (the "Letter").

**TOPIC NO. 2:**

**The identity of BARD's corporate officers and other employees (including but not limited to their titles, duties and dates of such responsibility) who were and are responsible for communicating with regulatory officials with the FDA and related regulatory bodies concerning the subject matter and content of the warning letter issued by FDA on July 13, 2015.**

**RESPONSE**:

Bard will produce a witness to testify generally concerning the identity of the individuals responsible for communicating with applicable regulatory bodies concerning the subject matter of the Letter.

**TOPIC NO. 3:**

**The visits/inspections from/by the FDA to Bard facilities on the dates listed in the warning letter issued by the FDA on July 13, 2015.**

**RESPONSE**:

Bard will produce a witness to testify generally concerning the FDA inspections and visits discussed in the Letter.

**TOPIC NO. 4:**

**The failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints associated with Bard's IVC filters and Bard IVC filter removal products as described in the warning letter issued by the FDA on July 13, 2015.**

**RESPONSE**:

Bard objects to this Topic as argumentative to the extent it assumes, as fact, that Bard "fail[ed] to establish and maintain procedures for receiving, reviewing, and

evaluating complaints." Although Bard is aware that the Letter contains such language, Bard contests that any such failure occurred as stated in the Letter.

Subject to the foregoing objection, Bard states that it will produce a witness to testify generally concerning Bard's procedures for receiving, reviewing, and evaluating complaints associated with its IVC filters and the claims made by FDA in the Letter regarding the same.

**TOPIC NO. 5:**

**Determination of lot numbers subject to the failure to establish and maintain procedures for acceptance of incoming product as described in paragraph 5 of the warning letter issued by the FDA on July 13, 2015.**

**RESPONSE**:

Bard objects to this Topic as argumentative to the extent it assumes, as fact, that Bard "fail[ed] to establish and maintain procedures for acceptance of incoming product." Although Bard is aware that the Letter contains such language, Bard contests that any such failure occurred as stated in the Letter.

Subject to the foregoing objection, Bard states that it will produce a witness to testify generally concerning Bard's procedures for the acceptance of incoming product from suppliers as discussed in Paragraph 5 of the Letter, and the claims made by FDA in the letter regarding the same. By way of further response, Bard notes that the Letter delineates the specific lot numbers that are at issue in the Letter, and Bard will produce a witness to testify generally concerning how those lot numbers were identified.

**TOPIC NO. 6:**

**The failure to submit reports as described in paragraph 7 of the warning letter issued by the FDA on July 13, 2015 and the responses submitted by Bard to the FDA listed as inadequate.**

**RESPONSE**:

Bard objects to this Topic as argumentative to the extent it assumes, as fact, that Bard "fail[ed]" to submit MDR reports to the FDA. While Bard acknowledges that the Letter identifies four complaints that Bard received for which Bard did not initially submit MDRs to the FDA, this alleged violation stated in Paragraph 7 of the Letter is an isolated



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incident that is not indicative of Bard's overall adverse event reporting practices and procedures.

Subject to the foregoing objection, Bard states that it will produce a witness to testify generally concerning Bard's adverse event reporting practices and procedures, Bard's actions and reporting concerning the four complaints identified in Paragraph 7 of the Letter, FDA's claims regarding the same as stated in Paragraph 7 of the Letter, and Bard's responses to the FDA concerning Paragraph 7 of the Letter.

**TOPIC NO. 7:**

**Actions taken by Defendants since the issuance of the warning letter issued by FDA on July 13, 2015.**

**RESPONSE**:

Bard objects to this Topic on the grounds that it is overly broad and unduly burdensome in that, taken literally, it seeks an individual who can testify regarding every single "action" taken by Bard since July 13, 2015. Bard further objects to this Topic on the grounds that its use of the term "actions" without any additional context is vague and ambiguous and subject to varying interpretations. Finally, Bard objects to this Topic to the extent it seeks information that is subject to the attorney-client privilege, work-product doctrine, or any other applicable privilege or immunity.

Subject to the foregoing objection, Bard states that it will produce a witness to testify generally concerning the communications that Bard has had with the FDA regarding the Letter after July 13, 2015, Bard's commitments to take certain steps to address the issues raised by the FDA in the Letter, FDA responses to such commitments, and the steps that Bard has taken to and plans to take to address the issues raised by the FDA in the Letter.

**REQUESTS FOR PRODUCTION IDENTIFIED IN EXHIBIT "B"**

**REQUEST NO. 1:**

**An unredacted and final copy of the warning letter issued by FDA on July 13, 2015 to Bard.**

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**RESPONSE**:

Bard has produced to the plaintiffs a copy of the FDA's July 13, 2015 Warning Letter to Bard. Said document was produced at Bates number BPV-17-01-00204231 through BPV-17-01-00204243.

**REQUEST NO. 2:**

**All communications with FDA related to the subject matter of the warning letter issued by the FDA on July 13, 2015.**

**RESPONSE**:

Bard objects to this Request as vague and ambiguous with respect to the term "related to the subject matter of the warning letter issued by the FDA on July 13, 2015." Taken literally, this Request could be interpreted as demanding production of all communications that Bard has ever had with the FDA regarding any of its IVC filters and/or the Recovery® Cone, regardless of whether such communications are directly related to the Letter. Additionally, such a Request is overly broad because it exceeds the scope of allowable discovery under the Court's October 30, 2015 Case Management Order No. 2 ("CMO No. 2"), as well as it exceeds the scope of the discovery that Bard has consistently stated that it would offer to the plaintiffs. Indeed, as early as October 1, 2015, Bard offered to produce all communications with the FDA concerning the FDA's 483 Letters and Warning Letter, including Bard's responses to the same. Bard further proposed to produce a Rule 30(b)(6) witness for a deposition concerning the topics identified in the plaintiffs' Notice, which the plaintiffs had previously provided to Bard. Bard then stated that, after such discovery, the parties could meet and confer regarding any additional discovery on those topics that the plaintiffs deemed necessary. Bard's counsel's understanding after that October 1, 2015 meeting was that the plaintiffs' counsel was amenable to Bard's proposals. Thus, consistent with those proposals, Defense counsel during the October 29, 2015 Case Management Conference stated that Bard would produce all "communications back and forth between Bard and the [FDA] beginning with the issuance of the 483 letters in January up to the present date." Case Mgmt. Conf. Tr.

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120:7-10 (Oct. 29, 2015). Although the plaintiffs' counsel asked the Court for a broader production, *see id.* at 122:4 - 123:18, the Court agreed with Bard's proposal. Indeed, the Court's October 30, 2015 CMO No. 2 orders Bard to produce "the documents described by defense counsel during the case management conference related to the FDA investigation and warning letter." CMO No. 2, at p.3 (Oct. 30, 2015). It further provides that the plaintiffs may "take a Rule 30(b)(6) deposition with respect to the FDA investigation and warning letter" by January 16, 2016. *Id.* All other discovery in this MDL has been stayed. *See* CMO No. 1. Finally, CMO No. 2 contemplates a "Second Phase of Discovery," during which the parties must meet and confer and may seek, among other things, "[f]urther discovery related to the FDA inspection and warning letter." Thus, the Court's CMO No. 2 contemplates an initial, defined approach to discovery regarding the FDA's 483 Letters and Warning Letter, as opposed to the expansive and virtually limitless approach sought after by the plaintiffs in their Notice and Request. The plaintiffs Request exceeds the parameters of discovery ordered by the Court.

Notwithstanding the foregoing, Bard notes that it has previously produced to the plaintiffs Bard's 510(k) submissions and associated official correspondence files for its retrievable IVC filters, including the Recovery®, G2®, G2® Express, Eclipse®, and Meridian® Filters. Said documents are categorized and listed by Bates number on the index provided by Bard to the plaintiffs' counsel on November 20, 2015.

In light of the foregoing objections, Bard states that, in accordance with the Court's CMO No. 2, it has searched for and produced to the plaintiffs copies of all of Bard's written communications to and from the FDA concerning the FDA's November 25, 2014 and January 5, 2015 483 Letters to Bard, and FDA's July 13, 2015 Warning Letter to Bard. The timeframe of communications that Bard searched and produced spans from October 2014 through December 3, 2015. Said documents have been produced at Bates numbers BPV-17-01-00193330 through BPV-17-01-00204480 and BPV-17-01-00205165 through BPV-17-01-00206171, and Bard notes that it provided the plaintiffs with a comprehensive index of said documents on November 16, 2015, and supplemental indices



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on December 2, 2015, and December 3, 2015. Finally, Bard states that it has not searched for nor is producing any documents in response to this Request beyond those identified via the aforementioned search parameters.

**REQUEST NO. 3:**

**All documents which reflect a regulatory log of contacts with the FDA regarding the warning letter issued by FDA on July 13, 2015.**

**RESPONSE**:

Bard has produced to the plaintiffs a copy of its FDA Contact Log concerning communications regarding the FDA's July 13, 2015 Warning Letter. The Contact Log was produced at Bates number BPV-17-01-00200590.

**REQUEST NO. 4:**

**All complaint files referenced in the warning letter issued by FDA on July 13, 2015.**

**RESPONSE**:

Bard objects to this Request as overly broad because it exceeds the scope of allowable discovery under the Court's October 30, 2015 Case Management Order No. 2 ("CMO No. 2"), as well as it exceeds the scope of the discovery that Bard has consistently stated that it would offer to the plaintiffs. Indeed, as early as October 1, 2015, Bard offered to produce all communications with the FDA concerning the FDA's 483 Letters and Warning Letter, including Bard's responses to the same. Bard further proposed to produce a Rule 30(b)(6) witness for a deposition concerning the topics identified in the plaintiffs' Notice, which the plaintiffs had previously provided to Bard. Bard then stated that, after such discovery, the parties could meet and confer regarding any additional discovery on those topics that the plaintiffs deemed necessary. Bard's counsel's understanding after that October 1, 2015 meeting was that the plaintiffs' counsel was amenable to Bard's proposals. Thus, consistent with those proposals, Defense counsel during the October 29, 2015 Case Management Conference stated that Bard would produce all "communications back and forth between Bard and the [FDA] beginning with the issuance of the 483 letters in January up to the present date." Case Mgmt. Conf. Tr.



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120:7-10 (Oct. 29, 2015). Although the plaintiffs' counsel asked the Court for a broader production, *see id.* at 122:4 - 123:18, the Court agreed with Bard's proposal. Indeed, the Court's October 30, 2015 CMO No. 2 orders Bard to produce "the documents described by defense counsel during the case management conference related to the FDA investigation and warning letter." CMO No. 2, at p.3 (Oct. 30, 2015). It further provides that the plaintiffs may "take a Rule 30(b)(6) deposition with respect to the FDA investigation and warning letter" by January 16, 2016. *Id.* All other discovery in this MDL has been stayed. *See* CMO No. 1. Finally, CMO No. 2 contemplates a "Second Phase of Discovery," during which the parties must meet and confer and may seek, among other things, "[f]urther discovery related to the FDA inspection and warning letter." Thus, the Court's CMO No. 2 contemplates an initial, defined approach to discovery regarding the FDA's 483 Letters and Warning Letter, as opposed to the expansive and virtually limitless approach sought after by the plaintiffs in their Notice and Request. The plaintiffs Request exceeds the parameters of discovery ordered by the Court.

On the basis of its objections, Bard states that it has not searched for nor is producing in response to this Request any documents.

**REQUEST NO. 5:**

**All complaint files provided to and/or reviewed by FDA as part of the investigation and inspections that resulted in the warning letter issued by FDA on July 13, 2015.**

**RESPONSE**:

Bard objects to this Request as overly broad because it exceeds the scope of allowable discovery under the Court's October 30, 2015 Case Management Order No. 2 ("CMO No. 2"), as well as it exceeds the scope of the discovery that Bard has consistently stated that it would offer to the plaintiffs. Indeed, as early as October 1, 2015, Bard offered to produce all communications with the FDA concerning the FDA's 483 Letters and Warning Letter, including Bard's responses to the same. Bard further proposed to produce a Rule 30(b)(6) witness for a deposition concerning the topics identified in the plaintiffs' Notice, which the plaintiffs had previously provided to Bard. Bard then stated



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that, after such discovery, the parties could meet and confer regarding any additional discovery on those topics that the plaintiffs deemed necessary. Bard's counsel's understanding after that October 1, 2015 meeting was that the plaintiffs' counsel was amenable to Bard's proposals. Thus, consistent with those proposals, Defense counsel during the October 29, 2015 Case Management Conference stated that Bard would produce all "communications back and forth between Bard and the [FDA] beginning with the issuance of the 483 letters in January up to the present date." Case Mgmt. Conf. Tr. 120:7-10 (Oct. 29, 2015). Although the plaintiffs' counsel asked the Court for a broader production, *see id.* at 122:4 - 123:18, the Court agreed with Bard's proposal. Indeed, the Court's October 30, 2015 CMO No. 2 orders Bard to produce "the documents described by defense counsel during the case management conference related to the FDA investigation and warning letter." CMO No. 2, at p.3 (Oct. 30, 2015). It further provides that the plaintiffs may "take a Rule 30(b)(6) deposition with respect to the FDA investigation and warning letter" by January 16, 2016. *Id.* All other discovery in this MDL has been stayed. *See* CMO No. 1. Finally, CMO No. 2 contemplates a "Second Phase of Discovery," during which the parties must meet and confer and may seek, among other things, "[f]urther discovery related to the FDA inspection and warning letter." Thus, the Court's CMO No. 2 contemplates an initial, defined approach to discovery regarding the FDA's 483 Letters and Warning Letter, as opposed to the expansive and virtually limitless approach sought after by the plaintiffs in their Notice and Request. The plaintiffs Request exceeds the parameters of discovery ordered by the Court.

This Request is also overly broad, unduly burdensome, and disproportionate to the needs of the case, given the vast expansiveness of the Request (which demands production of all complaint files "reviewed by FDA as part of the investigation and inspections"), particularly considering that the issues raised by the FDA in its 483 Letters and FDA Warning Letter have little or no relevance in this litigation. Bard further objects to this Request because it seeks information or material that is outside of Bard's possession, custody, or control, to the extent it seeks materials "reviewed by FDA." Bard notes that it

does not know the precise documents or materials reviewed by FDA during its investigation and inspections.

On the basis of its objections, Bard states that it has not searched for nor is producing in response to this Request any documents.

**REQUEST NO. 6:**

**All documents and materials provided to and/or reviewed by FDA as part of the investigation and inspections that resulted in the warning letter issued by FDA on July 13, 2015.**

**RESPONSE**:

Bard objects to this Request as overly broad because it exceeds the scope of allowable discovery under the Court's October 30, 2015 Case Management Order No. 2 ("CMO No. 2"), as well as it exceeds the scope of the discovery that Bard has consistently stated that it would offer to the plaintiffs. Indeed, as early as October 1, 2015, Bard offered to produce all communications with the FDA concerning the FDA's 483 Letters and Warning Letter, including Bard's responses to the same. Bard further proposed to produce a Rule 30(b)(6) witness for a deposition concerning the topics identified in the plaintiffs' Notice, which the plaintiffs had previously provided to Bard. Bard then stated that, after such discovery, the parties could meet and confer regarding any additional discovery on those topics that the plaintiffs deemed necessary. Bard's counsel's understanding after that October 1, 2015 meeting was that the plaintiffs' counsel was amenable to Bard's proposals. Thus, consistent with those proposals, Defense counsel during the October 29, 2015 Case Management Conference stated that Bard would produce all "communications back and forth between Bard and the [FDA] beginning with the issuance of the 483 letters in January up to the present date." Case Mgmt. Conf. Tr. 120:7-10 (Oct. 29, 2015). Although the plaintiffs' counsel asked the Court for a broader production, *see id.* at 122:4 - 123:18, the Court agreed with Bard's proposal. Indeed, the Court's October 30, 2015 CMO No. 2 orders Bard to produce "the documents described by defense counsel during the case management conference related to the FDA investigation and warning letter." CMO No. 2, at p.3 (Oct. 30, 2015). It further provides

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that the plaintiffs may "take a Rule 30(b)(6) deposition with respect to the FDA investigation and warning letter" by January 16, 2016. *Id.* All other discovery in this MDL has been stayed. *See* CMO No. 1. Finally, CMO No. 2 contemplates a "Second Phase of Discovery," during which the parties must meet and confer and may seek, among other things, "[f]urther discovery related to the FDA inspection and warning letter." Thus, the Court's CMO No. 2 contemplates an initial, defined approach to discovery regarding the FDA's 483 Letters and Warning Letter, as opposed to the expansive and virtually limitless approach sought after by the plaintiffs in their Notice and Request. The plaintiffs Request exceeds the parameters of discovery ordered by the Court.

This Request is also overly broad, unduly burdensome, and disproportionate to the needs of the case, given the vast expansiveness of the Request (which demands production of all documents and materials "reviewed by FDA as part of the investigation and inspections"), particularly considering that the issues raised by the FDA in its 483 Letters and FDA Warning Letter have little or no relevance in this litigation. Bard further objects to this Request because it seeks information or material that is outside of Bard's possession, custody, or control, to the extent it seeks materials "reviewed by FDA." Bard notes that it does not know the precise documents or materials reviewed by FDA during its investigation and inspections.

In light of the foregoing objections, Bard states that, in accordance with the Court's CMO No. 2, it has searched for and produced to the plaintiffs copies of all of Bard's written communications to and from the FDA concerning the FDA's November 25, 2014 and January 5, 2015 483 Letters to Bard, and FDA's July 13, 2015 Warning Letter to Bard. The timeframe of communications that Bard searched and produced spans from October 2014 through December 3, 2015. Said documents have been produced at Bates numbers BPV-17-01-00193330 through BPV-17-01-00204480 and BPV-17-01-00205165 through BPV-17-01-00206171, and Bard notes that it provided the plaintiffs with a comprehensive index of said documents on November 16, 2015, and supplemental indices on December 2, 2015, and December 3, 2015. Finally, Bard states that it has not searched

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for nor is producing any documents in response to this Request beyond those identified via the aforementioned search parameters.

**REQUEST NO. 7:**

**All internal communications relating to the subject matter of the warning letter issued by FDA on July 13, 2015.**

**RESPONSE**:

Bard objects to this Request as overly broad because it exceeds the scope of allowable discovery under the Court's October 30, 2015 Case Management Order No. 2 ("CMO No. 2"), as well as it exceeds the scope of the discovery that Bard has consistently stated that it would offer to the plaintiffs. Indeed, as early as October 1, 2015, Bard offered to produce all communications with the FDA concerning the FDA's 483 Letters and Warning Letter, including Bard's responses to the same. Bard further proposed to produce a Rule 30(b)(6) witness for a deposition concerning the topics identified in the plaintiffs' Notice, which the plaintiffs had previously provided to Bard. Bard then stated that, after such discovery, the parties could meet and confer regarding any additional discovery on those topics that the plaintiffs deemed necessary. Bard's counsel's understanding after that October 1, 2015 meeting was that the plaintiffs' counsel was amenable to Bard's proposals. Thus, consistent with those proposals, Defense counsel during the October 29, 2015 Case Management Conference stated that Bard would produce all "communications back and forth between Bard and the [FDA] beginning with the issuance of the 483 letters in January up to the present date." Case Mgmt. Conf. Tr. 120:7-10 (Oct. 29, 2015). Although the plaintiffs' counsel asked the Court for a broader production, *see id.* at 122:4 - 123:18, the Court agreed with Bard's proposal. Indeed, the Court's October 30, 2015 CMO No. 2 orders Bard to produce "the documents described by defense counsel during the case management conference related to the FDA investigation and warning letter." CMO No. 2, at p.3 (Oct. 30, 2015). It further provides that the plaintiffs may "take a Rule 30(b)(6) deposition with respect to the FDA investigation and warning letter" by January 16, 2016. *Id.* All other discovery in this MDL

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has been stayed. *See* CMO No. 1. Finally, CMO No. 2 contemplates a "Second Phase of Discovery," during which the parties must meet and confer and may seek, among other things, "[f]urther discovery related to the FDA inspection and warning letter." Thus, the Court's CMO No. 2 contemplates an initial, defined approach to discovery regarding the FDA's 483 Letters and Warning Letter, as opposed to the expansive and virtually limitless approach sought after by the plaintiffs in their Notice and Request. The plaintiffs Request exceeds the parameters of discovery ordered by the Court.

This Request is also overly broad, unduly burdensome, and disproportionate to the needs of the case, given the vast expansiveness of the Request (which demands production of all internal communications "relating to the subject matter of the warning letter"), particularly considering that the issues raised by the FDA in its 483 Letters and FDA Warning Letter have little or no relevance in this litigation. This Request is also objectionable as vague, ambiguous, and subject to varying interpretations with respect to the phrase "relating to the subject matter of the warning letter." Taken literally, this Request could be interpreted as demanding production of all documents that "relate" to any Bard IVC filter, Bard's complaint handling practices and procedures (regardless of what product is at issue), Bard's manufacturing processes, controls, and inspections (again, regardless of what product is at issue), and other broad topics that are "related to" the FDA's Warning Letter. Finally, Bard objects to this Request to the extent it seeks documents that are subject to the attorney-client privilege, work-product doctrine, or any other applicable privilege or immunity.

On the basis of its objections, Bard states that it has not searched for nor is producing in response to this Request any documents.

**REQUEST NO. 8:**

**Communications with FDA and internally since the issuance of the warning letter issued by FDA on July 13, 2015 which pertain to the subject matter and content of said warning letter.**

**RESPONSE**:

Bard objects to this Request to the extent it seeks "internal[]" communications, on



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the grounds that such a Request is as overly broad because it exceeds the scope of allowable discovery under the Court's October 30, 2015 Case Management Order No. 2 ("CMO No. 2"), as well as it exceeds the scope of the discovery that Bard has consistently stated that it would offer to the plaintiffs. Indeed, as early as October 1, 2015, Bard offered to produce all communications with the FDA concerning the FDA's 483 Letters and Warning Letter, including Bard's responses to the same. Bard further proposed to produce a Rule 30(b)(6) witness for a deposition concerning the topics identified in the plaintiffs' Notice, which the plaintiffs had previously provided to Bard. Bard then stated that, after such discovery, the parties could meet and confer regarding any additional discovery on those topics that the plaintiffs deemed necessary. Bard's counsel's understanding after that October 1, 2015 meeting was that the plaintiffs' counsel was amenable to Bard's proposals. Thus, consistent with those proposals, Defense counsel during the October 29, 2015 Case Management Conference stated that Bard would produce all "communications back and forth between Bard and the [FDA] beginning with the issuance of the 483 letters in January up to the present date." Case Mgmt. Conf. Tr. 120:7-10 (Oct. 29, 2015). Although the plaintiffs' counsel asked the Court for a broader production, *see id.* at 122:4 - 123:18, the Court agreed with Bard's proposal. Indeed, the Court's October 30, 2015 CMO No. 2 orders Bard to produce "the documents described by defense counsel during the case management conference related to the FDA investigation and warning letter." CMO No. 2, at p.3 (Oct. 30, 2015). It further provides that the plaintiffs may "take a Rule 30(b)(6) deposition with respect to the FDA investigation and warning letter" by January 16, 2016. *Id.* All other discovery in this MDL has been stayed. *See* CMO No. 1. Finally, CMO No. 2 contemplates a "Second Phase of Discovery," during which the parties must meet and confer and may seek, among other things, "[f]urther discovery related to the FDA inspection and warning letter." Thus, the Court's CMO No. 2 contemplates an initial, defined approach to discovery regarding the FDA's 483 Letters and Warning Letter, as opposed to the expansive and virtually limitless approach sought after by the plaintiffs in their Notice and Request. The plaintiffs Request

exceeds the parameters of discovery ordered by the Court.

This Request is also overly broad, unduly burdensome, and disproportionate to the needs of the case, given the vast expansiveness of the Request (which demands production of all internal communications "which pertain to the subject matter and content of said warning letter"), particularly considering that the issues raised by the FDA in its 483 Letters and FDA Warning Letter have little or no relevance in this litigation. Finally, Bard objects to this Request to the extent it seeks documents that are subject to the attorney-client privilege, work-product doctrine, or any other applicable privilege or immunity.

In light of the foregoing objections, Bard states that, in accordance with the Court's CMO No. 2, it has searched for and produced to the plaintiffs copies of all of Bard's written communications to and from the FDA concerning the FDA's November 25, 2014 and January 5, 2015 483 Letters to Bard, and FDA's July 13, 2015 Warning Letter to Bard. The timeframe of communications that Bard searched and produced spans from October 2014 through December 3, 2015. Said documents have been produced at Bates numbers BPV-17-01-00193330 through BPV-17-01-00204480 and BPV-17-01-00205165 through BPV-17-01-00206171, and Bard notes that it provided the plaintiffs with a comprehensive index of said documents on November 16, 2015, and supplemental indices on December 2, 2015, and December 3, 2015. Finally, Bard states that it has not searched for nor is producing any documents in response to this Request beyond those identified via the aforementioned search parameters.

**REQUEST NO. 9:**

**Documents reflecting actions taken by defendants as a result of the warning letter issued by FDA on July 13, 2015.**

**RESPONSE**:

Bard objects to this Request as overly broad because it exceeds the scope of allowable discovery under the Court's October 30, 2015 Case Management Order No. 2 ("CMO No. 2"), as well as it exceeds the scope of the discovery that Bard has consistently stated that it would offer to the plaintiffs. Indeed, as early as October 1, 2015, Bard

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offered to produce all communications with the FDA concerning the FDA's 483 Letters and Warning Letter, including Bard's responses to the same. Bard further proposed to produce a Rule 30(b)(6) witness for a deposition concerning the topics identified in the plaintiffs' Notice, which the plaintiffs had previously provided to Bard. Bard then stated that, after such discovery, the parties could meet and confer regarding any additional discovery on those topics that the plaintiffs deemed necessary. Bard's counsel's understanding after that October 1, 2015 meeting was that the plaintiffs' counsel was amenable to Bard's proposals. Thus, consistent with those proposals, Defense counsel during the October 29, 2015 Case Management Conference stated that Bard would produce all "communications back and forth between Bard and the [FDA] beginning with the issuance of the 483 letters in January up to the present date." Case Mgmt. Conf. Tr. 120:7-10 (Oct. 29, 2015). Although the plaintiffs' counsel asked the Court for a broader production, *see id.* at 122:4 - 123:18, the Court agreed with Bard's proposal. Indeed, the Court's October 30, 2015 CMO No. 2 orders Bard to produce "the documents described by defense counsel during the case management conference related to the FDA investigation and warning letter." CMO No. 2, at p.3 (Oct. 30, 2015). It further provides that the plaintiffs may "take a Rule 30(b)(6) deposition with respect to the FDA investigation and warning letter" by January 16, 2016. *Id.* All other discovery in this MDL has been stayed. *See* CMO No. 1. Finally, CMO No. 2 contemplates a "Second Phase of Discovery," during which the parties must meet and confer and may seek, among other things, "[f]urther discovery related to the FDA inspection and warning letter." Thus, the Court's CMO No. 2 contemplates an initial, defined approach to discovery regarding the FDA's 483 Letters and Warning Letter, as opposed to the expansive and virtually limitless approach sought after by the plaintiffs in their Notice and Request. The plaintiffs Request exceeds the parameters of discovery ordered by the Court.

This Request is also overly broad, unduly burdensome, and disproportionate to the needs of the case, given the vast expansiveness of the Request (which demands production of documents "reflecting" "actions taken by defendants as a result of the warning letter"),

particularly considering that the issues raised by the FDA in its 483 Letters and FDA Warning Letter have little or no relevance in this litigation. Bard further objects to this Request on the grounds that its use of the term "actions" without any additional context is vague and ambiguous and subject to varying interpretations. Finally, Bard objects to this Request to the extent it seeks documents that are subject to the attorney-client privilege, work-product doctrine, or any other applicable privilege or immunity.

In light of the foregoing objections, Bard states that, in accordance with the Court's CMO No. 2, it has searched for and produced to the plaintiffs copies of all of Bard's written communications to and from the FDA concerning the FDA's November 25, 2014 and January 5, 2015 483 Letters to Bard, and FDA's July 13, 2015 Warning Letter to Bard. The timeframe of communications that Bard searched and produced spans from October 2014 through December 3, 2015. Said documents have been produced at Bates numbers BPV-17-01-00193330 through BPV-17-01-00204480 and BPV-17-01-00205165 through BPV-17-01-00206171, and Bard notes that it provided the plaintiffs with a comprehensive index of said documents on November 16, 2015, and supplemental indices on December 2, 2015, and December 3, 2015. Said documents include materials that reflect the steps taken by Bard in response the FDA's July 13, 2015 Warning Letter. Finally, Bard states that it has not searched for nor is producing any documents in response to this Request beyond those identified via the aforementioned search parameters.

**REQUEST NO. 10:**

**Observations noted on FDA Forms 483, Lists of Inspectional Observations that were issued to you at the close of the FDA's inspections that are referenced in the warning letter issued by FDA on July 13, 2015.**

**RESPONSE**:

Bard has produced copies of FDA's November 25, 2014 and January 5, 2015 483 Letters to Bard. Said documents were produced at Bates numbers BPV-17-01-00193330 through BPV-17-01-00193336, and BPV-17-01-00193349 through BPV-17-01-00193358.

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This 3rd day of December, 2015.

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**CERTIFICATE OF SERVICE**

I HEREBY CERTIFY that the above and foregoing has been served by First Class postage prepaid U.S. Mail on December 3, 2015, to the following:

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